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CNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Brc. 1450 Alexandra, Virginia 22313-1450

| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------|-----------------------|---------------------|----------------------|---------------------|------------------|
| 09/932,277 | 09/932,277 08/17/2001 | | Peter H. Seeberger | MTV-034.01 | 3096 |
| 25 (8) | 7590 | 06/23/2004 | | EXAMINER | |
| FOLEY HO | | P ORLD TRADE CEN | LEUNG, JE | NNIFER A | |
| 155 SEAPORT BLVD | | | TERC WEST | ART UNIT | PAPER NUMBER |
| BOSTON, N | MA 0211 | 0 | 1) n | 1764 | |

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | <u> </u> | | | | | |
|--|---|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| | 09/932,277 | SEEBERGER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Jennifer A. Leung | 1764 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 08 Ja | anuary 2003. | | | | | |
| 2a) This action is FINAL . 2b) ⊠ This | action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-58 is/are pending in the application. 4a) Of the above claim(s) 31-58 is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-30 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-58 are subject to restriction and/or expressions. | n from consideration. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine 10)☒ The drawing(s) filed on <u>08 January 2002</u> is/are: Applicant may not request that any objection to the o Replacement drawing sheet(s) including the correction 11)☐ The oath or declaration is objected to by the Ex | a)⊠ accepted or b)⊡ objected or b) objected or b) objected or b) objected or abeyance. See ion is required if the drawing(s) is objected or by in a comparison is required if the drawing(s) is objected or b). | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6-17-02. | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other: | | | | | |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-30, in the reply filed on January 3, 2004 is acknowledged. The traversal is on the ground(s) that,

"... simultaneous examination of Inventions I and II would not place an undue burden on the Examiner because the claims of Invention II are limited to methods practiced in an apparatus of claim 1, i.e., Invention I."

This is not found persuasive. As stated in the prior Office Action, the process of oligosaccharide synthesis may be practiced in a materially different apparatus from that which is claimed -- namely the apparatus disclosed in U.S. Patent No. 5,466,608. Additionally, the process and apparatus as claimed are distinct, each from the other, as evidenced by their separate classifications. Both of these reasons suffice as proof that the simultaneous examination of Inventions I and II would present an undue burden on the Examiner. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 31-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Drawings and Specification

3. The lengthy drawings and specification have not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is unclear as to the structural relationship of "a reaction vessel" to the other elements of the apparatus. (i.e., the Examiner suggests inserting the phrase, -- to the reaction vessel -- , after the word "solvent" in line 8).

Regarding claim 22, it is unclear as to the structural relationship of the "at least one blocking vessel" to the other elements of the apparatus.

Claim Rejections - 35 USC § 102 and/or 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1, 17 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hudson et al. (EP 0 355 266).

Regarding claim 1, Hudson et al. discloses an apparatus comprising:

- a reaction vessel (i.e., reaction column 17; FIG. 1) containing at least one insoluble resin bead (i.e., Pepsyn K or polystyrene solid supports; column 9, lines 53-54);
- a plurality of different reservoirs R1, R2, R3, R4, R5 and R6 for containing one or more reagents (column 7, lines 22-39);
- a solution transfer system (i.e., fluid transport system 15, with manifold 79 and a plurality of connecting conduits; FIG. 1) capable of transferring the one or more reagents from reservoirs R1, R2, R3, R4, R5 and R6 to the reaction vessel 17; and
- a computer for controlling the solution transfer system (i.e., an electronic control/computer including board 18; FIG. 1).

Hudson et al. further illustrates the operation of the apparatus by disclosing an exemplary operation involving solid phase peptide synthesis,

- wherein at least one of the reservoirs R1, R2, R3, R4, R5 and R6 inherently comprise "a donor vessel" containing a donor solution, as evidenced by the provision of a solution of "Fmoc amino acid," (column 9, lines 11-29);
- wherein at least one of the reservoirs R1, R2, R3, R4, R5 and R6 inherently comprise "an activator vessel" containing an activating reagent solution, as evidenced by, "... activating and coupling the amino acid as follows: 0.5 mmol of the Fmoc-amino acid, BOP and HOBt mixture is dissolved in 2.5 ml of activator and coupled to 0.1 mmol of support," (column 9, line 57 to column 10, line 3; column 10, step 10);

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wherein at least one of the reservoirs R1, R2, R3, R4, R5 and R6 inherently comprise "a deblocking vessel" containing a deblocking reagent solution, as evidenced by the, "Initial deblock of the resin [being] achieved with 30% piperidine in DMF for 10 minutes," (column 9, lines 54-57; column 10, step 6); and

wherein at least one of the reservoirs R1, R2, R3, R4, R5 and R6 inherently comprise "a solvent vessel" containing a solvent, as evidenced by the deblock procedure being, "... followed by 6-10 washes with DMF," (column 9, lines 5-10, 54-57).

Hudson et al. is silent as to whether the contents of the donor vessel may instead comprise a saccharide donor solution, such that the apparatus may be used for synthesizing oligosaccharides. In any event, Hudson et al. indicates that the disclosed apparatus has utility in numerous applications, including the synthesis of oligosaccharide assemblies, due to its accurate dissolution, dispensing and reaction of chemicals. (column 1, lines 3-20). Thus, the apparatus of Hudson meets the claims. [Note: a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963)]. Furthermore, Hudson et al. states that the disclosed methods of operation are exemplary only, and different synthesis and equivalent apparatus may be substituted for that disclosed, where appropriate. (column 12, lines 43-50). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select a saccharide donor solution for the disclosed donor solution in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing

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oligosaccharide assemblies and absent showing any unexpected results thereof.

Regarding claims 17 and 19, the apparatus of Hudson et al. inherently comprises at least one solvent vessel containing dichloromethane or methanol (column 12, step 20).

Instant claims 1, 17 and 19 structurally read on the apparatus of Hudson et al. or, in alternative, are obvious over the apparatus of Hudson et al.

6. Claims 2-5, 8-14, 18, 20, 21, 26-28 and 30 are rejected under 35 U.S.C. 103(a) as being obvious over Hudson et al. (EP 0 355 266) in view of Seeberger et al. (US 6,323,339).

Regarding claims 2 and 30, Hudson et al. is silent as to the at least one insoluble resin bead having a glycosyl acceptor tethered to the resin bead via an organic linker, including an organic linker of glycosyl phosphate. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select another known, suitable type of insoluble resin bead for a reaction substrate in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing oligosaccharide assemblies, since the apparatus is disclosed as being capable of utilizing different substrates for performing its intended use, and furthermore, the substitution of known equivalents merely involves ordinary skill in the art.

Seeberger et al. evidences the use of such resin beads for the synthesis of oligosaccharides by teaching a variety of solid supports (column 9, lines 44-63) to which the glycosyl donor or the glycosyl acceptor is attached, wherein the connection of the first monosaccharide to the support is accomplished through a linker that leaves a hydroxyl group after cleavage from the solid support or through a spacer elements which is connected through the anomeric position as an alcohol (generally, column 8, line 14 to column 9, line 41; Scheme 5).

Regarding claims 3-5, Hudson et al. is silent as to the apparatus further comprising a

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temperature control unit for regulating the temperature of the reaction vessel, wherein the unit is capable of measuring the internal temperature of the reaction vessel and capable of being controlled by the computer. Seeberger et al. teaches that in the synthesis of oligosaccharides, the reaction zone may be fitted with one or more internal and/or external heat exchanger(s) in order to control undue temperature fluctuations, or the prevent any possible "runaway" reaction temperatures (column 31, lines 50-55). It is important to control the temperature of the reaction because, "... the reaction temperature influences the speed of the reaction, as well as the stability of the reactants, products and catalyst," (column 30, lines 61-65). It would have therefore been obvious for one of ordinary skill in the art at the time the invention was made to provide a temperature control unit to the apparatus of Hudson et al., in order to control undue temperature fluctuations and prevent any possible runaway reactions, as taught by Seeberger et al. above.

Regarding claims 8 and 9, Seeberger et al. teaches that while the synthesis of oligosaccharides may be conducted over a wide range of conditions, "it will be desirable that reactions are run using mild conditions which will not adversely affect the reactants, the catalyst or the product," (column 30, lines 55-65), wherein the coupling reaction on the solid phase or in the solution phase should be carried out in apparatus capable of achieving a temperature as low as -40 °C (column 12, lines 40-47). For example, the coupling reaction of anomeric β -phosphates is conducted under a temperature -78 °C and the coupling of α -phosphates is conducted under a temperature of -20 °C (column 47, line 1 to column 48, line 8). In any event, it would have been obvious for one of ordinary skill in the art to configure the temperature control unit to operate within a desired temperature range in the modified apparatus of Hudson et al., because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

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the optimum or workable ranges involves only routine skill in the art.

Regarding claims 10 and 11, Hudson et al. is silent as to the at least one donor vessel containing a solution comprising glycosyl trichloroacetamidate or glycosyl phosphate. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select another known, suitable, donor solution in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing oligosaccharides, since the apparatus is disclosed as being capable of utilizing different donor solutions for performing its intended use, and furthermore, the substitution of known equivalents merely involves ordinary skill in the art. Seeberger et al. evidences the use of such donor solutions for the synthesis of oligosaccharides. In particular, "tricholoracetimidates have been used for over fifteen years for the synthesis of oligosaccharides in solution and very recently on the solid support," (column 1, lines 51-58). Additionally, Seeberger et al. teaches the use glycosyl phosphates as building blocks for oligosaccharide libraries, since glycosyl phosphates are extremely powerful glycosyl donors that can be efficiently synthesized from differentially protected glycal precursors that are commercially available (column 4, lines 22-52; column 21, lines 16-27).

Regarding claims 12-14, Hudson et al. is silent as to the at least one activator vessel containing a solution comprising a Lewis acid, a solution comprising silyl trifluoromethane-sulfonate or a solution comprising trimethylsilyl trifluoromethanesulfonate. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select another known, suitable, activating reagent solution in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide, since the apparatus is disclosed as being capable of utilizing different activating reagent solutions for

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performing its intended use, and furthermore, the substitution of known equivalents merely involves ordinary skill in the art. For instance, Seeberger et al. evidences the use of such solutions by teaching the synthesis of oligosaccharides under reaction conditions comprising a Lewis acid (column 18, lines 25-63), a silyl triflate (column 19, line 36 to column 20, line 6) or trimethylsylil triflate (column 20, line 44 to column 21, line 14).

Regarding claim 18, Hudson et al. is silent as to the at least one solvent comprising tetrahydrofuran. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select another known, suitable solvent in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide, since the apparatus is disclosed as being capable of utilizing different solvents for performing its intended use, and substitution of known equivalents merely involves ordinary skill in the art. Seeberger et al. evidences the use of such solvents for the synthesis of oligosaccharides. In particular, Seeberger et al. teaches the reaction may be carried out in an inert solvent, preferably one in which the reaction ingredients are substantially soluble. Suitable solvents include ethers such as tetrahydrofuran and the like (column 30, line 66 to column 31, line 14).

Regarding claims 20 and 21, although the combined teachings of Hudson and Seeberger et al. are silent as to the vessels containing the specifically recited combination of reactants and solvents, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select an appropriate combination of reactants and solvents in the modified apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide, because where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable conditions involves only routine skill in the art.

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Regarding claim 26, the same comments with respect to Hudson et al. and Seeberger et al. apply (see claims 2 and 3 above).

Regarding claims 27 and 28, although the combined teachings of Hudson et al. and Seeberger et al. are silent as to the vessels containing the specifically recited combination of reactants and solvents, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select an appropriate combination of reactants and solvents in the modified apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide, because where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable conditions involves only routine skill in the art. Additionally, the apparatus of Hudson et al. is disclosed as being capable of utilizing a variety of reactants. Thus, it would have therefore been obvious for one of ordinary skill in the art at the time the invention was made to provide the recited fourth and fifth solvent vessels to the modified apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide.

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being obvious over Hudson et al. (EP 0 355 266) in view of Seeberger et al. (US 6,323,339), as applied to claim 3 above, and further in view of Hood et al. (US 4,610,847).

Hudson et al. discloses that, "fluid conduits, valve components, manifolds, reservoirs and other components coming into contact with the fluids being handled by the system are made for a material inert to the fluids, such as Teflon, polypropylene, polyethylene and stainless steel (column 8, lines 40-45). Additionally, Seeberger et al. teaches that the synthesis of oligosaccharides should be conducted in either glass lined, stainless steel or similar type equipment,

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with one or more internal and/or external heat exchangers (column 31, lines 50-55). However, the collective teachings of Hudson et al. and Seeberger et al. are silent as to the reactor vessel comprising a glass, double-walled structure forming two cavities, wherein the first cavity accommodates the reaction and the second cavity accommodates a coolant of the temperature control unit. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to substitute another known, suitable reactor for the reactor vessel in the modified apparatus of Hudson et al., on the basis of suitability for the intended use, because substitution of known equivalent structures merely involves ordinary skill in the art. For example, Hood et al. presents a conventionally known reaction vessel (i.e., conversion flask 14; FIG. 14-16) suitable for conducting sequential chemical reactions, wherein the reaction vessel is of the double-walled glass type having a space 264 between the walls for the circulating of a heat exchange medium and an interior space 270 for conducting the reaction.

8. Claims 15 and 29 are rejected under 35 U.S.C. 103(a) as being obvious over Hudson et al. (EP 0 355 266) in view of Seeberger et al. (Solid-Phase Oligosaccharide Synthesis: Preparation of Complex Structures Using a Novel Linker and Different Glycosylating Agents).

Regarding claims 15, Hudson et al. is silent as to the deblocking reagent comprising sodium methoxide. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select another known, suitable, deblocking reagent solution in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide and absent showing any unexpected results thereof, since the apparatus is disclosed as being capable of utilizing different deblocking reagent solutions for performing its intended use, and furthermore, the substitution of known equivalents merely involves ordinary

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skill in the art. Seeberger et al. evidences the use sodium methoxide in the synthesis of oligosaccharides by teachings the, "Removal of the C2-acetate protecting group by treatment with sodium methoxide in methanol" in order to "[liberate] a support-bound acceptor moiety to undergo the sequential coupling and deprotecting steps." (page 1813, column 2, paragraph 2).

Regarding claim 29, Hudson et al. is silent as to the at least one insoluble resin bead comprising an octenediol functionalized resin. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select another suitable insoluble resin bead in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing oligosaccharide assemblies, since the apparatus is disclosed as being capable of utilizing different substrates for performing its intended use, and furthermore, the substitution of known equivalents merely involves ordinary skill in the art. Seeberger et al. evidences the use of octenediol functionalized resins in the synthesis of oligosaccharides in order to, "provide rapid access to β -(1 \rightarrow 4)- and β -(1 \rightarrow 6)-linked trisaccharides in high stepwise coupling yields and short reaction times," (page 1812, column 1, paragraph 2).

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Hudson et al. (EP 0 355 266) in view of Bendiak (US 5,403,927).

Hudson et al. is silent as to the deblocking reagent solution comprising hydrazine. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select another known, suitable, deblocking reagent solution in the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide and absent showing any unexpected results thereof, since the apparatus is disclosed as being capable of utilizing different deblocking reagent solutions for performing its

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intended use, and furthermore, the substitution of known equivalents merely involves ordinary skill in the art. For instance, Bendiak evidences the use of hydrazine as a deblocking reagent, relating to the sequential removal of monosaccharides from the reducing end of oligosaccharides, by teaching the, "cleaving [of] the glycosidic bond between the former reducing end monosaccharide and the adjacent monosaccharide of the oligosaccharide using a hydrazine, thereby completing the removal of the former reducing end monosaccharide," (column 3, lines 46-66; also, column 12, lines 25-55).

10. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being obvious over Hudson et al. (EP 0 355 266) in view of Urdea et al. (US 5,256,549).

Hudson et al. is silent as to the apparatus further comprising at least one blocking vessel containing a blocking reagent solution, such as a solution comprising benzyl trichloroacetimidate or a solution comprising a carboxylic acid, i.e., levulinic acid. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide at least one blocking vessel to the apparatus of Hudson et al., on the basis of suitability for the intended use of synthesizing a desired oligosaccharide, because the use of such reagents for providing selectively blocked, protected or capped terminal functionalities during the coupling reaction of monomers (i.e., thereby minimizing error sequences in the final oligomer) is well known in the art, as evidenced by Urdea et al. (see carboxylic acid capping groups, preferably levulinyl; or benzyl protecting groups; column 13, lines 3-68; column 15, line 58 to column 16, line 54).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is (571) 272-1449.

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The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on (571) 272-1444. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer A. Leung June 15, 2004

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